

**HIT Standards Committee
Consumer Technology Workgroup
Transcript
August 23, 2013**

Presentation

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Consumer Technology Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, this meeting is being transcribed and recorded, so please state your name before speaking. I'll now take roll. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President, Policy – Healthwise

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Brian Carter?

Brian Carter – Executive Strategist – Cerner Corporation

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Arthur Henderson?

Arthur R. Henderson – President – Affinity Networks, Inc.

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Brian Ahier?

Brian Ahier – President – Gorge Health Connect, Inc./Mid-Columbia Medical Center

I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

John Ritter?

John Ritter, MS – Software Engineer – Co-Chair, EHR Workgroup

John Ritter's here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Anshuman Sharma? Susan Hull?

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

Present.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Mohit Kaushal? AJ Chen?

AJ Chen, PhD – Chair, Data Committee – National Partnership for Action Region IX Health Equity Counsel

I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Tonya Dorsey?

Tonya Dorsey – Chief Implementation Architect – Blue Cross Blue Shield of South Carolina

I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

John Derr?

John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Yair Rajwan? Tom Jones? Liz Johnson? Christine Bechtel? Marcia Nizzari? Fred Trotter? Russ Leftwich?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Holly Miller? David Harlow? Wes Rishel?

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Susan Woods? Kim Nazi?

Kim Nazi, PhD, FACHE – Management Analyst – Veterans Health Administration

I'm here, thank you.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

And are there any ONC staff members on the line?

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor – Office of the National Coordinator

Ellen Makar's here.

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator

Mary Jo Deering is here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Thank you. And I will turn it over to you Leslie.

Leslie Kelly Hall – Senior Vice President, Policy – Healthwise

Super. Well thank you everyone for joining. We have a great deal to discuss today and to learn, and some deadlines coming up. Our emphasis in these past few meetings has really been about getting all of us up to speed on what's happening in the standards world today, with a specific emphasis on what is needed to support both Meaningful Use 2 and Meaningful Use 3 coming up. And so today we are going to hear two speakers, one from our own team, Russ Leftwich, who will talk about the harmonization of standards for patient engagement and then also from Dr. David Kibbe, who will talk about Direct and patient – and consumer's interaction with Direct. We will then have time for Q&A and discussion and then we are going to have another meeting on August 28 where we'll have Lisa Nelson from HL7 discuss patient-generated health data, as well as Chuck Parker from Continua, who will be talking to us a little bit about standards and devices.

Our goal is to have some recommendations by the end of September, to do a joint meeting with the policy – Consumer Policy Group in October, in order to meet the timeline for recommendations going forward for Meaningful Use 3. Our September meeting will be dedicated really around making our recommendations and decisions. So with that, I will just go to the next slide, and to remind everyone of our charge and what we're attempting to do. And next slide – and our participants, which we have a great deal of you on board today, so, thank you. And next slide. We – I just reviewed that, sorry. Next slide.

Okay, we had some questions that we need to consider, and that is what standards are needed to support the flow and use of patient-generated health data through all parties including how is patient-generated health data accepted? These are questions that have come from the policy group and also as we've been discussing. What are use cases around PHR to EHR or other document submissions? How is Direct used with patient and patient portals, or other secure messaging? We've also been tasked with looking at vocabulary that might be needed in the future, and that's not being teed up for our discussions and recommendations for Meaningful Use 3 as yet, we will look at that more future time. Next slide please.

So we have to make sure that we are very knowledgeable of what is necessary in patient-generated health data that's already incorporated in Meaningful Use 2, what standards have been recommended already in policy and standards for Meaningful Use 3, and then what the Meaningful Use 3 standards have been proposed. So we're really looking at all of these things in our previous meetings and our next two meetings. Next slide please.

So our next steps, really we are going to focus a lot on patient-generated health data and harmonization of that and hopefully report out in discussion on August 28 and then again in September. And then once we've answered those questions, we want to know what the maturity and adoptability of all these standards are and what will their projected level of maturity and adoptability be by 2014 and 2015. So we'll be looking at both long range and short term. It's important because there is a bias, and so should be, to use existing standards, but we also want to make sure that we aren't curtailing or in any way prohibiting patient engagement, but we're actually using standards to promote patient engagement. Next slide. So with that, I'm going to turn it over to our presenters. First up is Dr. David Kibbe.

David Kibbe, MD, MBA – President & CEO – DirectTrust

Thank you Leslie and thank you committee members for inviting me to come and talk with you this afternoon. I'm going to be speaking with you today about Direct Exchange from provider to patient/consumer in terms of Blue Button Plus. But then I also want to spend a little time talking about bi-directional exchange, what we need to have that in place and some of the ways in which the DirectTrust Security and Trust Framework has made it possible and is mature enough now, I think, to handle both of those scenarios. Next slide please.

So I think most folks know that DirectTrust is a Security and Trust Framework provider that has developed this framework in support of Direct Exchange. Our goals being to make it possible for eligible providers and patients and anyone who really wants or needs a direct address, to be able to seamlessly and ubiquitously and easily connect with other addressees who are part of the Direct network. DirectTrust is also the recipient of an ONC cooperative agreement, which was awarded in March in the amount of \$280,000 dollars, as part of what is known as the Exemplar HIE Governance Program. And we're very happy to be continuing to work even more closely now with ONC on these efforts to increase interoperability between electronic health records and among electronic health records and other applications. Next slide please.

So what I would like to do in the 15 minutes I've got allotted is fairly quickly moved through these four questions and issues. The first is to describe to you the DirectTrust approach to establish scale and trust between parties in Direct Exchanges. And to point out how this supportive of Blue Button Plus and is rapidly becoming if not a standard, a mature framework that can be thought of as a set of standards and policies within the industry that supports Direct Exchange in an interoperable and scalable way. I want to explain and get down a little bit into the details enough so that I can describe to you Blue Button as a use case and why it is out – only for – in most instances from provider to patient and consumer. There are some things about this that you need to understand with respect to privacy, security and trust-in-identity controls to understand why this is generally the case. I'll rapidly go over what I think are a few gaps or limitations of the use case of Blue Button Plus and then talk about the opportunities for bi-directional Blue Button, I'm calling it Blue Button 2 Plus, because I think there's a significant amount of market movement already in that direction.

Next slide please. This slide attempts to schematically show the approach that DirectTrust's members, which now total a little over 90, have developed as an approach to scaling trust and to do that in a standards based way to assure privacy and security for Direct Exchange, which after all, takes place over the Internet, which is an inherently insecure environment. And I just want to state that one of the really important things to keep in mind about this is that Direct Exchange will be moving protected personal health information, it needs to be very secure and the parties involved need to keep this information very secure at all times. So that approach involves first of all a Security and Trust Framework, these are policies and best practices and guidances, they are the rules of the road, if you will, that have been consensually and transparently developed by first the Direct Rules of the Road Workgroup and then the members of DirectTrust.

That framework has been utilized and leveraged to create an accreditation and audit program for HISPs, Certificate Authorities and Registration Authorities, in partnership with EHNAC, who is the entity that actually performs the accreditation process and the audit using the policies and criteria that have been developed and continue to be developed by DirectTrust members. And then finally DirectTrust offers a trust anchor bundle distribution service that makes it very easy and inexpensive for the HISPs who are accredited, to share each other's trust anchors in order to facilitate what we call scalable trust. And I'll touch on that – why that's such an important part of this, in some ways; it's sort of the payoff of the energy and effort that goes into becoming accredited. Next slide please.

So I just want to point out in this slide, I'm not going to go over every piece of it, but that there really are three separate roles and responsibilities that need to be played by trusted agents and combined to enable Direct Exchange to occur. This is some of the background that a lot of people still don't quite understand, but there is a Registration Authority role, that is the entity that compiles and validates identity and trust documentation. That information needs to be passed to the certificate authority and whoever is playing that role is the entity that issues the X.509 Certificate that are used for validating identity and encrypting and decrypting messages in Direct Exchange. And then finally, the Health Information Service Provider of HISP is the entity that sets up the address and binds the unique address of an individual and/or an organization to a particular X.509 Certificate.

And I just want to point out that there is a chain of trust here. All three of these entities need to be aligned with respect to their privacy and security controls. Now, it's important also to know, and probably everyone here knows that, multiple organizations can play these roles or a single organization can play these roles. So we have some cases where electronic health record companies are playing all three of them, and we have situations in which electronic health record and/or personal health record companies and vendors are playing just the role of HISP and outsourcing the RA and CA roles to other parties. And it's also important to – finally to point out that the healthcare organization and the individuals who have addresses rely upon these trusted agents to do their privacy and security and do it well, because if they don't then there is a risk of privacy breach and/or security failure. Next slide please.

Now the trust anchor bundle is really an important part of this. The trust bundle that DirectTrust has established now is – now has ten accredited HISPs trust anchors in it and that means that there are 90 separate connections between those ten HISPs and they link over a thousand healthcare organizations to the DirectTrust network. We don't know exactly how many addressees those thousand healthcare organizations are – have, but it's quite a lot. There's not a tremendous amount of exchange going on, as you all know, but much of this is readiness for Stage 2 Meaningful Use. These HISPs shown below are now able to exchange with one another by virtue of having each other's trust anchor in each individual HISP's trust store, and I'll talk about that a little later as well. And what this is creating then is a network of parties who can, as a network allows them to do, communicate with everybody else on the network without further negotiation or contracts having to be signed or entered into by the various parties. Okay, so next slide.

So then this technology and trust framework is mature now and it supports Direct Exchange of various kinds. Here what I'm showing is a direct exchange between providers engaged in Stage 2 Meaningful Use Programs. So on the bottom left you have Dr. Bob, who's been identity-vetted and has an X.509 Digital certificate bound to his address and let's suppose that he's trying to send a referral through his Epic electronic health record, through Surescripts acting as the HISP over to Dr. Susan, who's a cardiologist who will receive the referral information from Dr. Bob. And in this case you have two HISPs that have to connect with one another. Note on the right Cerner is performing both of these roles. Please do the next build. And this attempts to get at this idea that for Dr. Bob and Dr. Susan to communicate via Direct, both of their HISPs have to have each other's trust anchor in its trust store. If it doesn't, the exchange will not go through and that's an important point to recognize, that when Dr. Bob tries to communicate with Dr. Susan, if the trust anchor from Surescripts isn't in Cerner's, as a HISP, trust store, the connection cannot be made. So, next slide.

And here's where we get the Blue Button Plus, because this same technology and the same trust work – trust framework, also supports Blue Button Plus, but only as an outbound from the EHR to patient's receiving system and I'm going to explain to you why. So in this case we have Dr. Susan on the left and she's sending information to John Doe at Direct.MyPHR.net. And although Dr. Susan has been identity vetted, it is not necessarily the case and the Blue Button paradigm at this point, doesn't assume that John Doe has been identity vetted. He has an X.509 Digital certificate, but it's bound only to a non-verifiable address. And so this means that there's an asterisk on the trust anchor of John Doe – John Doe's HISP, shown over in the Cerner HISP on the left. And that asterisk represents the fact that this is essentially a sequestered trust anchor that's used only for moving data from the sending system that Dr. Susan uses to the personal health record or application that in this case, John Doe uses. Next slide please.

So, here are the gaps in the Blue Button Direct Exchange. So as it is currently configured, although this, as I'll address in a minute, this is not necessarily always going to be the case. The direct address that's supplied by the patient's HISP and used by the patient consumer is not necessarily a verifiable endpoint. That is, if the certificate bound to that address was issued at NIST level of assurance 1, it means only that that person has a control of email address but no proof of identity, in other words, nothing like a driver's license has been presented to the CA issuing that certificate as a requirement of issuing that certificate. Next slide – or next build please.

So the other issue is that trust is not only about identity. Currently the personal health records in the Blue Button Plus ecosystem do not make any verifiable assertion of privacy and security controls being in place for trust anchors placed in the Blue Button Plus anchor bundles. And that creates a potential risk for inbound messages from those sources. And I think that's really the heart of – these two points here are the heart of the reason that Blue Button Plus is seen as – by all of the experts and security experts and all of the HISP's that we have come in contact with, within DirectTrust, and even outside in the federal agencies as well, as an outbound only type of service. And next – please. So that's the basis of why most provider HISP's restrict Blue Button Plus to outbound only direct messages, which is fine. I mean, that serves purpose, that's terrific.

However, I think there's an opportunity now, next slide please, to go beyond Blue Button Plus fairly rapidly to bi-directional exchange. As a matter of fact, in DirectTrust, we now have a handful, maybe two handfuls, of consumer-oriented vendors who are what I would call next generation personal health record companies. And what makes them different is that they one, are asserting HIPAA compliance, even though they are not a certificate covered entities. In the past, some PHR companies, as you know, have not wanted to be HIPAA compliant. Secondly, they are offering identity verification at LoA 2 or 3, prior to the issuance of direct address certificates, for patients and consumers. In other words, they're building Direct Exchange into their products, but they're doing so at a level of identity verification, which makes it more likely, at least in my mind, and I think in their business models, that provider organizations will permit those patients who have these higher-level credentials to both send and receive direct messages with providers.

And thirdly, they're reason for joining DirectTrust is because they are seeking a pathway towards EHNAC DirectTrust accreditation as HISP's, CAs and RAs for patients, consumers and citizens. And I would mention a couple of these companies are serving not only the needs of patients and consumers, but also providers. And then then final build there, please, so I consider these new product offerings – it's hard to know what to call them, they don't like to call themselves personal health records, they like to call themselves medical information homes or platforms for patient health information and they feature Direct as one of their product offerings. Next slide, next build. So I think bi-directional Direct Exchange is going to gain momentum during 2014, you will see more and more of these companies entering the marketplace, getting funding, wanting to do bi-directional Direct Exchange between patients and others, the provider organizations. And I believe we'll probably accredit at least one or two of these organizations by early 2014. And I think that's the end of my presentation. Next slide. I'd be delighted to talk with anybody about any of these issues and I hope I've stayed within my 15 minutes.

Leslie Kelly Hall – Senior Vice President, Policy – Healthwise

Well we added – we have time for discussion – a few questions? Are there any comments or questions from the group?

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Wes Rishel –

M

This is Brian. Thanks David and I guess I just want to ask a leading question and that is about DirectTrust and the formation – and actually the work of what the workgroup is doing around patients.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Well, the person to talk to about that of course is Leslie, who's one of the co-chairs of the workgroup; it's the Citizen and Patient Participation in Direct Workgroup. I think we've been, as a group, to answer your question and maybe Leslie wants to follow up with that, we've been working on these policies for about a year now and we have some recommendations to make that would support, I think, the kinds of things we're seeing in the marketplace now.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Wes Rishel.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Go ahead Wes.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Hey David.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Hi Wes.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

I – first of all, I think you deserve tremendous commendation for charting a path through too complicated and too easy to getting DirectTrust.org to be like the baby bear, just right, okay?

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

You're very kind, thanks.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

And that's no small accomplishment in a field where we tend to all be papa bears and go overcomplicated. Second, I think you deserve a minor accolade for having put together the single most coherent and easy to understand presentation on what DirectTrust is all about; it's remarkable for both its simplicity and its cogency. I'm –

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

I just want say this, this is a collaborative group, we inherited the spirit of Direct – the Direct Project and I think it's kept it alive.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

I agree and I think – I'm – it's enough buttering you up at this point, I won't go on, but I think everyone needs to recognize the importance of what DirectTrust is and why it – without it the technology would not be that useful. I'm fairly new to the committee and as you know, when you heard me speak in California recently, I'm sort of a side of the road conversion, due to my experience with personal health applications, which are in some sense a different category than a personal health record.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Yup.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

But it works out they end up having many of the same characteristics, for example, my current food logging application gets data from FitBit and would no doubt like to be able to get data from my electronic health record in order to do a better job of coaching me. And in effect becomes a – one of many repositories that are out there of some subset of my personal health data. Now I think we're – we on the committee are looking at alternate models for relating the electronic health record to the various kinds of applications that somehow enable consumers to be engaged, to take more control of their own health decisions and to work more effectively with their physicians while being engaged. And two of the models that are on the table right now are effectively bi-directional DirectTrust and OAuth 2, which we heard about in the past and does not require the personal application to actually have a vetted identity. It only requires that the personal application go through a standard kabuki dance with the EHR in order to determine that the personal health representation was being – has been invoked by a person that the health organization, the EHR recognizes as a patient.

The benefits of the DirectTrust approach are clear, I think, or some of them are clear in that it creates an easier job of persuading the operator of an EHR to release patient data. The benefits of the DirectTrust approach are that it is not so constraining on the innovative market out there that has brought us things like FitBit and so forth. Do you have any sense of how we should balance sort of the ability to invite very unregulated applications into the patient's circle of exchange versus the need for that doubly vetted identity at both ends of a link?

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Yeah, well, that's a great question. I mean, you're probably going to not be surprised by my answer. Much of this is cultural; much of this is really about finding a way that's acceptable to providers and provider organizations to start to move the data in the direction that patients want it to go. And that to me is probably just as important as the technology, that the – that we have to crawl before we can walk, and we have to walk before we can run. And if you ask me how this is going to work out, I think one of the really startling things we'll discover is that as patients and consumers can use what we'll call a patient portal, an electronic means of software to ask for their health information, and receive it, this is really going to start to takeoff.

Because one of the barriers right now is, if I want medical records from my orthopedic surgeon, it's going to take me half a day. I'm going to have to go in there, I'm going to have to fight with the people because they don't want to give me my medical records, it's embarrassing and I'd rather probably go to the dentist and have a root canal. And it think what you're suggesting is that the genie's out of the bottle in terms of thinking about really innovative ways that information might be gotten from monitoring devices, for example, to an electronic health record and from an electronic health record to those applications running on those patient's devices. And I love to think about that, but it really has been a lot of work just to get the Direct Protocols up and running at any – with any chance of acceptance in the marketplace. So I think we're quite a ways from many of these other forms of communication that are pretty common on the Internet, but gosh, healthcare's still using paper primarily, right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Are there other questions, I have one if there aren't any. I'm sure there are, we have plenty of time to discuss this. Comments or questions?

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

This is Susie Hull. Thanks for a great presentation and great to hear you again after we were together out here in Santa Rosa, California.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Yeah, that was a nice conference, wasn't it?

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

Very nice. Brian, Wes, David, myself, there might be others on the call who were there. But my question is, help me understand, you're not using the term consumer-mediated exchange at all in your presentation and I'm just curious about the specificity of your word choice and helping me understand if you think that's a next step in this bi-directional. And the context I'm coming from is I've been working with a colleague, Dr. Hon Pak on a virtual health wallet with the ability to do this bi-directional exchange and really try to drive towards more preference-sensitive care, and exchanging from the consumer perspective into an EHR or into a community portal off of an HIE. Those are some of the models we've been working with, but I'm just wondering if that's an intentional omission in your conversation and help me understand, give me a teaching moment here.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Well, I'm a pretty simple person in a lot of ways and I'm not sure what the term means yet, patient-mediated, so it's fine, and if others want to use it and they know what it means, that's great. I chose not to use it because I don't really know what it means. My perspective here is that we've just got to get the data out of the electronic health record into places where patients can consume that information and use it. And we've got to allow channels back into the medical practices for patients or consumers so that they can get answers to questions that don't require visits, for example. And – the names that we put to that bi-directional exchange, that communication, that sharing of information, isn't real important to me. If you like it, I like it, too.

Leslie Kelly Hall – Senior Vice President, Policy – Healthwise

So I –

AJ Chen, PhD – Chair, Data Committee – National Partnership for Action Region IX Health Equity Counsel

I have one question, this is AJ. David, I would like to get your thoughts on this simple alternative that seems possible from the BB Plus API approach. So, in your graph, so you're assuming that two doctors, Dr. Susan and Dr. John and so – and they have their own EHR. If I put a BB Plus API in front of each of the EHRs and with that, Dr. Susan can send anything through the EHR to the EHR API on the other side directly and vice versa, Dr. John can do the same thing. So essentially, this exchange, the information exchange can be enabled with simply just install an API in front of the EHR, without going through any of those trust network. So this is an alternative, I just want to get – technology – it's possible and it also takes care of all the security issues that have been – that may be, I'm just wondering how do you think of this new alternative.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Well, I'm glad to learn about it, it's really the first time I've heard about it. I think it sounds wonderful, I'm all for new technology. The Direct Project specified a set of protocols and specifications for Direct Exchange, but that is not a standard. All the electronic health records for Stage 2 Meaningful Use, actually, that's incorrectly said, all electronic health records for the 2014 edition of the standards and certification criteria have to be enabled to do Direct. So I think it's a pretty stunning opportunity being put in front of us that these products now, because of the government's standardization here, are going to be capable of doing this particular exchange. I think that's – if there are other alternatives that come into the marketplace, that's fine, but I've been pretty much heads down trying to get this one to work.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Wes Rishel.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Go ahead Wes.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

I'd like to challenge the premise of that last question and in particular, the notion that the API solves all of the problems of interconnecting the EHRs. It's the same comment that I made about the relationship between DirectTrust and the Direct Protocol. The APIs can mediate various of the issues that have to be solved to make trust work, but they don't get to that – they don't directly, and without additional organizational and not inexpensive organizational support. They don't get to that fundamental issue of if I'm Dr. Susan, and I'm sending something – if I'm Dr. Bob and I'm getting something from Dr. Susan, how do I know that Dr. Susan is not really a dog on the Internet? That requires not just the use of certificates – the technology that's being employed now, but it causes some ability to know that I trust the entity that issued the certificate and that I trust Dr. Susan's organization to have reasonable policies and software in place to avoid there being technical artifacts that would betray the confidence of the patient.

Sort of the classic instance that people like to talk about is a storefront in San Diego that's called Joe's Endoscopy Shack and – but the fundamental issue is that with all of the work that we did on Direct and the protocol and making it tight and making it economic and all of that. If David and EHNAC – if DirectTrust and EHNAC hadn't put together this process of certifying the certificate holders, accrediting the certificate holders and a simple way of exchanging what can grow to be dozens or hundreds or millions of certificates over time, but the technology wouldn't have been any good. And that's no different with regards to the Blue Button Plus API. We still need to know we can trust the other player.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Wes, if I could comment on your comment and link it back to your earlier one. I'd like to hope that the Security and Trust Framework that has been developed by DirectTrust members could be repurposed for different technologies. So in reference to your question about, are there other innovative technologies that might be used, I think your comments are really well taken. It may in fact be that the trust and identity and security controls are going to be important to them, too, regardless of the technology.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And – this is Leslie – and I think that’s – when I hear these discussions and I hear the – an API approach or bi-directional Direct approach or OAuth 2, it strikes me that really regardless, as you say David, of the technology, there has to be a trusted framework. So I want to put that as a given, but I’m trying to understand and distinguish between approaches like a bi-directional, high-level of assurance, Direct address for a patient or an OAuth 2 approach. And in my simple mind, I think that really the OAuth 2 approach is bound to an account, it’s the authority associated with being able to grant permissions of an application is based upon the fact that the identity assurance has been done at an account or a portal level issued by the provider. And that provider knows that Leslie is their patient and I am connected to that account, just like I go to Wells Fargo, open up an account and then I can go online, establish my authorization through user ID and password and then attach to MINT.com. I have the ability, I’m the bridging mechanism and that my identity is really assigned to that account or that portal. But using Direct approach, my identity is bound to an address, not to an account and so that begins to say, is there a different level of need in healthcare when you have an address-bound identity and certificate and trust. And so my question to both Wes and David are, have I articulated that in a way that makes sense and if so, I’d like to hear your comments about that kind of approach or thought.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Well I would say very quickly that the Security and Trust Framework that DirectTrust members have developed could be reused or repurposed for the issuance of certificates that are used for other purposes besides the Direct purpose, right? I mean the Direct Protocol, the applicability statement sort of limits what you can do with a dual-purpose Direct certificate, it’s really – it’s limited to that exchange between HISP A and HISP B. But, there’s no reason why the information and the process of identity proofing and verification couldn’t be used to issue a different kind of credential or token.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Yeah, I’d like to agree with David completely on that point. And I think it’s important to separate the notion of a trusted identity from the protocol that’s being used –

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Yes.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

– on behalf of that trusted entity. The sort of technical emblem of that trusted identity is this Digital certificate that David has been discussing.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

But it’s – the underlying concept is the identity. And I think there are two models, one model is that both participants in an exchange of information have the identity of the same patient through one of these emblems – one of these certificates.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

\

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

The other model is that as a provider I know how I identify my patients, if they login to my portal and they do whatever authentication procedure I use, whether it's a password or having to call me or text me a message, whatever we choose to use to let people look at their data online. Any application that presents and enables the patient to do that same identification process for me, I'm willing to send data to that application, clearly whoever authenticated was the patient because those are the same rules and the same mechanism and everything else that I use to identify the patient. I don't care whether that other application knows the patient's true identity or only knows the patient as WRishel7821 because at that point, I have given the data to the patient, no different than if they had viewed it and done a print or downloaded it from my portal. The patient now has control of the data and I have assured myself, using the same mechanism, that that was really the patient. The latter approach is less restrictive on those other applications and – but – and we have a lot of need to discuss whether those restrictions are beneficial or not, but that does distinguish the two approaches.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Thank you. Are there other questions or comments from the group? So, I think this has been very helpful and really appreciate the participation. And I honestly believe that there is going to be further dialogue and future use cases we can anticipate and this is emerging. I think Susan, at a previous conference, described that our current state is black and white TV with vacuum tubes in the back and yet we can envision 3-D movies at this point, but we're still trying to figure out how to get the remote control to work. And I think that that's true, we're still – we're beginning and I just really appreciate the work that you've done, Dr. Kibbe, in helping us get this going and look forward to getting the remote control working and 3-D movies in the future. So, any other questions or comments. Okay, let's go forward. Russ?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Yes, and thank you. So, I'm going to talk about harmonization opportunities for standards relevant to patient and consumer engagement and patient-generated health data. It won't be really exhaustive and I will only refer to patient-generated health data indirectly, that's going to come up more extensively on August 28, and I'm going to focus on some of the near-term areas that I think are foundational to what comes next. So if I could have the next slide.

First I'll pick up the relevant history of harmonization starting a few years ago with what we thought of as harmonization then. Release 1 of the consolidated clinical document architecture standard of HL7 was really a harmonization of existing standards from IHE, from HITSP 32, Health Story and HL7. That standard, when balloted in HL7, produced some 3,000 ballot comments, an extended process of reconciliation. So fast-forward to this year and the 2013 Consolidated CDA update and the HL7 care plan domain analysis model, both of which are very relevant to this – the general topic here. And harmonization has really evolved to a process that we might call pre-coordination and that's thanks mostly to the S&I Frameworks efforts and influence. So the ballot materials for these two HL7 ballots in the current cycle have been developed by a collaborative effort between the Standards and Interoperability Framework, Longitudinal Coordination of Care Initiative Workgroups and other volunteers and the HL7 Structured Documents Workgroup and HL7 Patient Care Workgroup.

And much of this material in these ballots is new content, it's not, importantly I think, a matter of using existing standards, a lot of this, to my knowledge, really doesn't exist. So rather than harmonization of existing standards, it requires development and it's reasonable to assume that many of the comments that would have been generated by the ballots that are currently – have instead been resolved in the collaborative process of developing the ballot material, and there will be more of that in the future, very importantly. It may be that an equal amount of time went into this, but the timeline is really advanced and my observation from participating in this is that there was input from a much broader spectrum of stakeholders in this effort. The care – the next slide please.

The care plan domain analysis model is the modeling representation of the data and the workflows in a care plan or a care plan fragment such as a plan of care treat – or treatment plan. And included in that model is the care team for the individual. The concept of a care team is certainly not new and not in the HL7 domain it's not new, but it's developed around the concept of a care team that would operate within an organization and be represented in a single EHR system. The significance of that is that this is – the team members in that care team and their roles are known to the organization and their system IDs are really local to the organization. The concept – existing concept does include and recognize the role of family caregivers, although the attributes of that role are relatively limited. But the care team concept in the care plan domain analysis model that's been developed and – is one of a patient centered longitudinal care team that spans organizations and episodes of care. And it incorporates the concept of family and community caregivers and recognizes the need for unique identifiers for members of the care team who are health professionals, such as an NPI, so that they can easily be identified across organizations. The next slide.

So in developing this model, the data attributes for care team members that...include their role with respect to this particular patient. With exchange of care plans across organizations, this becomes important because that role may not be obvious from their license or job title. Other important concepts incorporated into this data element are the frequency of involvement of the care team member with the individual, is it a specialist who saw the individual two years ago, is it a care team member who regularly sees the individual or is it a primary caregiver in the home. So, a name and identifying information on a roster really don't provide this information, it's going to be very important in exchanging the care plan information that these attributes are there and are enabled. Other concepts in this data element would be the intensity of involvement of a care team member with a patient, whether the team member is only executing an assigned task or they're actually a decision maker. The individual's role in the governance of the care plan, whether they're a professional – health professional or a family caregiver. And perhaps even the last encounter or contact with a care team member so that that's apparent when the roster of care team members is exchanged. Next slide please.

So in the care plan domain model, there are also associations of team members with key data elements in that care plan, such as the health concern, the goals and the interventions, the data elements that are really the essence of a care plan. So health concern, which encompasses problems and conditions and other well-known concepts is really the act of being concerned about a clinical concept that's represented elsewhere in the record. Other attributes of the associations are priority that the team members assign to each of these data elements and the priority of different team members, including the provider, the patient and family caregivers may not align and those differences are really important to capture. And goals include the concept of authorship and acceptance or acknowledgement of the goal – of each goal and the data elements that represent those concepts really need to be included and are included in the domain model. Choice of interventions may be influenced by patient preference and family caregivers or providers may express preferences in terms of recommendations. The association with these elements for a care team member may also have a type of involvement, and again, the intensity or level of involvement. So, if I could have the next slide.

The importance of these roles and associations in terms of care coordination and patient and consumer engagement and involvement have been discussed and have become more and more apparent in developing the domain model. And as mentioned with the exchange of care plan elements across organizations, this requires metadata that may not be as important within an organization and has not really typically been represented in existing standards and therefore, as I said, needs to be developed, if you will. The specifics about care team members provide documentation for patients and caregivers, which really is otherwise typically non-existent or very difficult to gather. With patient access to their information the value of this, to me, is really profound, that patients and their families can have the roster and these attributes of the members of the care team that help to define what their relationship is to the patient. Studies have shown that individuals have very unreliable recall for hospitalizations and emergency visits and other encounters, more than six months in the past, and I think I would suggest that the same is true for recall of the names and contact information of providers involved in the past. And if you consider the value of this type of care team information and associated metadata to the involved family members who are not direct caregivers, like an adult child in another city, I think it's tremendous. And also the identification of the governance role of different care team members, both family caregivers and professionals, is really essential to the care planning process itself, and to appropriate communication and exchange of information.

I think it would – if information – communications are simply sent to everyone on the care team, it becomes cumbersome, it doesn't allow for the designation of access to data and it very likely would become overwhelming if everyone who's simply listed gets every communication or is asked to be involved in the care planning process. And relative to patient-generated health data, the context and method of generating the patient-generated health data, as well as the specific equipment that's involved is important to the provenance of this data, but equally so for the identity and the roles of family caregivers who may be the source of the data, particularly when it starts being exchanged across systems. The family caregivers may be known in the patient's medical home, but less likely to other systems involved in the patient's care. If I could have the next slide please.

So the other standard currently being balloted in HL7 that it's – the product of this pre-coordinated harmonization is the 2013 Consolidated CDA update. Which to remind you what's in release one of the Consolidated CDA it's the document templates that include the CCD, but also eight other document templates that are typical clinical documents that are represented in the CDA standard. In the 2013 CDA update, the release 2 that's being balloted, there's an update of the medications, the results, the problems, the demographics, the vital signs and other section entries. But very importantly, there are three new document templates, the transfer summary, particularly around the LTPAC transfers, there's a referral note and an updated consult note that will, I think, be much more valuable when those documents are exchanged. And when those documents are available to patients, there will be an indication of the purpose of that information, which is often not there if it's a clinical summary like a CCD, and the reason for the referral and the assessment in the consult.

There are also some updated and new sections that I think are very important to patient-generated health data, which may not appear so at first. But things like the functional status and cognitive status of the individual, that are new might well be provided by family caregivers and submitted as CDA document. Equipment is not a new section, but that too may be something that comes, for some things, from the patient's home environment as opposed to from the EHR system. If I could have the last slide.

So going forward, the 2013 CDA update and the care plan domain analysis model are really in the current HL7 ballot cycle, which closes 2000 – I'm sorry, closes September 14. And there's still the opportunity for those who are HL7 members or who want to comment and there's the possibility of participating by paying a fee, but there is still an opportunity to comment on the content of this – these standards. In the future, near future, the care coordination service functional model is expected to be balloted in the 2014 January ballot cycle. It's the model for the synthesis and exchange of care plan elements. It will be dependent on the care plan model and will really require development of some of the value sets, vocabularies for these care team attributes – care team member attributes, the role with respect to the patient, preferences and priorities.

So, I think those very important elements are to be harmonized over the coming months in this effort. And as I said, it may not be as much as harmonization as development of something new, but still there's this concept that's come out of the S&I Framework and the collaboration with HL7 and other standards development organizations of working together to produce something that's more valuable and more usable. And I think will be extraordinarily important to consumer engagement and to incorporating patient-generated data into systems and to bi-directional exchange, certainly.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So Russ – this is Leslie. So you really have done a great job of articulating sort of that future vision. So much is dependent right now in making sure that the definitions around the patients, their roles, associations and so forth are solid enough, because they will be then used to build things in the future like a care plan that's across team, across organization and including the family team members.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So – and you're then suggesting that the opportunity to do that is right now, and during these ballot cycles –

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

– and then also in – with regard to this team, those of us that are members of an HL7 – of HL7 to provide comment in these areas and also then to influence future harmonization. So, did I capulate that correctly?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Yeah, absolutely, I mean, I don't think a roster of a care team that's simply a list of individuals and contact information is sufficient when we star – particularly when we start exchanging it and neither for the organizations that are delivering care nor the individual, the patient, and their family. It's to me very important that we be able to communicate these relationships and associations between elements of the care plan amongst everybody on the care team.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And right now then, Michelle or Mary Jo might know this but, I'm afraid I've got too many meaningful use committees in my mind, but at some point in time, we had the care team roster or care team members listed as a requirement, I can't remember –

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Right.

Leslie Kelly Hall – Senior Vice President, Policy – Healthwise

– if that was in 2 or 3 or if it was certification only and where we are now.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

I think it's in 2, but it's just a text-based list of the care team, I think.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

So for 3 its proposed that it's just a free text field that will include the care team members.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And that's in 3, Michelle?

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Yes –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

– at least that's what the Meaningful Use Workgroup's proposing.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Wes Rishel.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So we then have an opportunity to inform that, based upon what information that Dr. Leftwich just gave us about how to make potentially that roster more meaningful in preparation for collaboration in the future and patient-generated health data.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Wes Rishel –

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Right and I –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Go ahead Russ.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

I just – I want to say again, I think that's extraordinarily important that we create a framework for this that will make this information much more valuable. And that the current effort is well along to actually do – well along the way to actually doing that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's great news. Are there other comments, questions?

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Wes Rishel.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

I wonder if Russ would agree that it's probably possible for non-members of HL7 to submit comments on ballots. I think that's the case.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

You have to sign up for the ballot pool and there is a small fee, yes.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Oh, okay. So there is a mechanism without paying full membership –

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Exactly.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

– I will say, it's a significant effort to review a ballot. Then I wonder if Russ would also suggest that another – whether increased participation in the S&I Framework would be valuable at this point or is that –

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Absolutely, I mean – and that is open and free, except for your time, and the collaboration that has developed and particularly has happened in this current ballot cycle is – I expect is so valuable that it will continue as a – what I’ve dubbed the pre-coordinated harmonization.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

And finally, I think we owe it to our parent committees to also plan to do a maturity evaluation similar to the kind of things that Dixie described, at some point in the process. It doesn’t necessarily need to go into shaping immediate plans for Stage 3, but certainly somewhere before regulations are produced, we need to make a maturity evaluation.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, I think we do and we have provided all the speakers of this week and next week and others the worksheet, and I think it’s an opportunity we can come back to, to have their self-evaluation and then have us go back, ask questions and create our own, as part of our recommendation. I think it’s a very, very important step, I agree wholeheartedly. Are there other comments and questions from the team?

AJ Chen, PhD – Chair, Data Committee – National Partnership for Action Region IX Health Equity Counsel

Yes, this is AJ. Russ, I have a question about the new development of HL7 regarding the FHIR. What is the relationship between FHIR and 2013 CCDAs development and just – try to understand the role at HL7.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

I am not a FHIR expert. I know that it is – there is a lot of excitement about FHIR amongst a number of the vendor and implementer communities. It is sometimes presented as an alternative to – or the next stage – phase beyond HL7 version 3, but reality is that they will certainly co-exist for the foreseeable future. And there may even be some implementation of using FHIR to create CDA documents, but I’m far from enough of an expert to explain that any further.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Does anyone else have any knowledge they can contribute to that? I believe in our presentation –

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

This is Wes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, go ahead Wes.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

This is Wes. I just want to say that I endorse Russ’ comment about them co-existing. I think that as FHIR become – gets to become a reality, which it’s not yet, we will see it used in use cases where there’s a desire to inquire on or transmit bits of data that are less than complete documents. And I think that in addition, it may appear as a transport mechanism for complete documents, but the important thing is that the underlying work that Russ describes contributes to both standards, it’s not either FHIR or CCDAs, it’s both.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

And I – the other place that I think FHIR will have considerable uptake as I understand is the mobile devices and their connection to EHR systems and other systems.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm. So, it’s fair to say that regardless of the type of delivery and the technology delivery, this idea of harmonization, especially with respect to the roles of the patient, the associations and preference in the priorities is work that will inform all of that, now and into the future.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
Yup.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And the opportunity for harmonization is very high and somewhat immediate, is that true?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives
Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Yes, very short term and the model, as Wes suggests, the model domain – care plan domain model will really inform all of these things, not just one standard.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great. Are there other questions or comments from the group?

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

This is Susie Hull, I have just three short comments. One, I really like the discussion that you led Russ on the circle of sharing for the care plan and the attributes around the providers and the patient and the family. I think another helpful construct is that the rhythm of participation for sharing the care plan will be different with the provider kind of network and the patient and family network. The patient and family network of sharing details and updates on the care plan and data in the care plan may be a tighter rhythm that providers who are looking at a longer term. So patients will have bursts of activity around a care goal or a readmiss – I mean a hospitalization and the post-care whereas providers will have a longer term rhythm. And it seems like one of the helpful constructs to add would be preferences, sharing preferences so that it would be just another attribute you would add to the provider network and to the patient network. And the ability for a distributed way for people to contribute their sharing preferences, as well as have patients really control their sharing preferences and different ti – in different ways over a period of time.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

And that is – has been discussed and is included in the model, although those sharing preferences overlap with consent in a way that separates them from other preferences, if you will.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Russ, does that – I think that's a really great point. We heard this week earlier in the Policy Workgroup, Consumer Policy Workgroup that the notion of consolidation of data, which really is a preference, a provider might say really, I want to see this on a monthly basis unless you're out of range so high that requires an encounter, I want to see this on a monthly basis. And the patient might want to share that particular data with their group every day, and this is how I'm doing, because their ability to stay in that current positive state might be to have community support. So, does this – so what you're saying is that notion of both cadence and preference for consolidation, so it's both frequency and breadth and depth. Is that all thought in the model currently?

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Well, it was – that was considered in constructing the model –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

– some of those things are policies and implementations, if you will, that really aren't directly part of the model, but are enabled by the model. And I think that gets back to the idea that you simply don't want to share everything with everyone on the care team because it becomes cumbersome and overwhelming.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So there's both preferences of the recipient and preferences of the sender.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Right. But sometimes the preferences of the recipient have to be determined by knowing their role –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Exactly.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

– that they were a one-time consultant or they were involved in a previous episode of care that's now ended, so therefore they logically don't get everything. But they're not going to tell you that, you have to know that based on their being able to identify what their relationship is to this patient.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's great. Any other comments or questions?

John Ritter, MS – Software Engineer – Co-Chair EHR Workgroup and Volunteer HL7

Sure, John Ritter has a question.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

Leslie, I just had two more quick ones, and I'll just make it very brief.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, and then we'll go to John.

Susan Hull, MSN, RN – Chief Executive Officer – Wellspring Consulting

Another concept is just the process for pushing out care plan updates and the patient actually accepting the updates to the care plan. And then the last comment was just considering perhaps in the evolution in the next year, is to look at care plan outcomes and care plan adherence as two other attributes that get driven in the model.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

And much of that will be part of this care coordination service functional model that will – has been balloted once and the S&I Framework was very much of the comments on that ballot. And we expect will be balloted a second time in January 2014, that is about the processes, if you will, as opposed to just the document that's a care plan.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So this is very interesting. I think it's perhaps an instance where the standards group is ahead of the policy. So, it might be worthwhile to do an overview for the next time we have a shared committee meeting between policy and standards. I heard John, you had a comment.

John Ritter, MS – Software Engineer – Co-Chair EHR Workgroup and Volunteer HL7

Sure, this is John Ritter, the EHR Workgroup co-chair and working on the personal health record system functional model. We're envisioning a couple other members of the care team like the circle of care being widened a bit to include social support networks. For example, if a parent has a child with special needs, they might join an organization of other parents who have the same sort of need to care for that child and they give each other advice and recommendations and pointers to literature. So this becomes a sort of non-professional extension of the care team. Another part of the care team could be, for example, if a child is hurt during an athletic event in college, the coach or the trainer or the athletic training department or the school nurse might need to be involved. Not that they're part of the professional care team, but they need to know what the professional care team is doing so they can make sure that the athlete recovers well. And then the third part would be a diet or nutrition coach or a team to help people control their weight. These might not be professionals, but they might have some sort of a paid membership that's helping coach the person on controlling their weight or their diet.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Yeah, and I guess that was – those concepts I included as community caregivers, not myself being aware of a good comprehensive term to include those extended care team members.

John Ritter, MS – Software Engineer – Co-Chair EHR Workgroup and Volunteer HL7

Yeah, in Canada they call it a Circle of Care, I think I like that term, because community caregivers seems to imply healthcare professionals in the community as opposed to hospital caregivers.

Russell Leftwich, MD – Chief Medical Informatics Officer –Tennessee Office of eHealth Initiatives

Except in Canada, it would be Circle of Care, eh, right?

John Ritter, MS – Software Engineer – Co-Chair HER Workgroup and Volunteer HL7

There you go. All right, back to you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Super. Any other comments or questions from the team for Russ? Okay, so we're going to move to just some discussion of the team. We've heard a lot so far and what I'd like to hear is your impressions, feedback, some preliminary ideas of recommendations that you might like to have considered as we go forward. So really open this up for discussion, not just on the items we've heard today, but the items we've heard in our previous sessions. So, it's an open discussion and who would like to start?

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Leslie, I was going to wait and let somebody else have a chance, but – this is Wes Rishel.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Go ahead Wes.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

If there's one thought that has come to my mind over the last couple of meetings that I've attended, it's been for us to include in our considerations the EHR, the PHR or medical data bank or other sort of highly authorized system that represents the patient and personal health applications. I think the distinctions between those three cases are worth examining and teasing out and then deciding, do we have a unified recommendation or do we have specific recommendations based on the sort of three different sets of relationships that exist between those three different kinds of systems.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's a really good point because absent that kind of striation, we're not quite sure where the policy levelers and the standards levers can be applied. So that's a really important thing to capture.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

Can I comment on that, this is David.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sure.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

In your workgroup Leslie, we have been working on some of that, because as organizations come forward Wes, to like helping circles for example, see – as a platform for providers and patients and anybody else who wants to participate in team care, and our mounting HISP's and seeking accreditation, we don't have a really good description for them. They aren't exactly personal health records in the same way that HealthVault of Dossia was or – .health was, in part because of the attributes that I listed in my second to last slide. Because they want to be HIPAA compliant, they want to be accredited with respect to their security and privacy – privacy and security and trust identity control and that – I think what we're doing in the DirectTrust Workgroup is a slice of that. But it's not as comprehensive as you outlined because I think it requires making sure we don't create any dead ends.

So, for example, we use these terms like patient portal, I'm not sure we really know what that is becoming. We know what it has been, but a patient portal that is Direct enabled may, in fact, become a patient's health information home that we used to call a tethered personal health record, but I don't think that gets close to it either, because it's much more than that. It is the potential to interact with medical devices, the potential to move information to medical devices and so forth. So I just want to second your idea here that this needs – this work needs to be done.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think that even to further that, given what Russ just presented, we have the, as you described Wes, the EHR and then the PHR that's sort of the authorized PHR or portal, the personal health apps and then a collaboration platform. All of these things are somewhat different, can all co-exist, but may have different use cases and assumptions around them and certainly different areas of standards and policy that apply. So I think it's very important to think about each one of those.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Yeah, I think what I'm hearing is, there are still some specific variances in the role of the system to be teased out –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

– particularly this notion of – I mean, even HealthVault historically was – had a goal of being the platform for many different applications that would update – that would read and possibly update patient's personal health record data. I used to call that the health record and those applications personal health management tools and I think Dossia very much built on the same model. I think that there are even other models developing now. But I think it's worth us teasing out even if it's the case of finding a bunch of cases and then finding the right way to combine them to simplify, I think it's worth us teasing that out and using that as a basis as we present other recommendations to the Policy Committee. Because absent understanding who the bilateral players are, you get into confusion about what would be the applicable policy or –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I agree.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

– the applicable standards for that matter.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I agree wholeheartedly, I think that's worth some work. Perhaps –

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Yeah, David McCallie and Dixie and I have been carrying on an offline thread since our meeting a couple of days ago on some of these points. I thought I might check with them and maybe share it with the committee if they're amenable.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That would be great. And I've also been talking a little bit about the strating HIEs, so it would be great to get all of that teased out in a conversation. Are there other items of concern or comment or just general opportunities from the group? Yes.

AJ Chen, PhD – Chair, Data Committee – National Partnership for Action Region IX Health Equity Counsel

This is AJ, I have two general comments in terms of the recommendations. I didn't really from the – community perspective or a developer perspective, so the one comment that this consumer technology health industry is a fast moving industry, and we are at the point that we actually don't really know what's going to happen, even next year. So when we – that really means that to me, if we make any policy recommendations or standards recommendations, you will not serve the purpose if you lock in to just one or two, without opening – without having some opportunity for unforeseen alternatives, new technology to add on. For example, I think the current Meaningful Use 2, for example, Meaningful Use 2 regulations essentially specifically require Direct as a transport mechanism. And I hope that we don't – that happen again in the future meaningful use requirements, because what if another new alternative that's just going to cost less, easy to actually to get adoption to make the meaningful use – much quicker and easier. So if we had foreseen that kind of thing to happen, so when there's a regulation, then we don't actually exclude that kind of possibility. So that's one comment and essentially it's very important for us working in the industry that try to innovate new things, if we even come up with a new thing, and that's suddenly – by the regulation, we're stuck. So, I hope that that won't happen; that's one.

The other thing is really about the adoption in the context of knowing what the industry are actually doing, particularly this young industry. So when we recommend standards, we need to understand what's the – we need to take into consideration that the standards are – whether the standards are understood and can be easily adopted by the developer community in the consumer technology industry. And to give you an example that for example, if I'm a – I'm actually a developer, so when I'm developing, looking at the health exchange landscape right now, if I look at Direct and I look at the BB Plus, so I'm looking at what I have already known, then I need to figure out what to choose from, right? And at this point, the industry, the consumer technology industry, most of the developers are really coming from the Internet industry, so they are immediately expect an API available. That's how they understand and how they operate.

So if they say API available for data exchange, bi-directional and that's the stuff we need to consider, so when they look at this – how to start to try to solve the problem at the healthcare arena, and they find out Direct is the only thing they can use, and they try to understand. They will spend time to understand it, but it may turn out that it's probably too complicated for people to understand, then you actually turn off a lot of the developers. And that will actually make adoption suffer, meaning, the develo – the adoption in the developer community will be slow, if you don't recommend something that can be easy to understand or actually, has been in the – that's already common in their standard tool sets, or at least something similar. So I just wanted to say that the second point is really to try to under – take into account what the people, the developers who are actually going to develop a tool on those standards, make sure that our standards propose recommendations actually are something that can be easily adopted, understood by the developer community. That's my two points.

Leslie Kelly Hall – Senior Vice President, Policy – Healthwise

Great. Thank you AJ. I think that that is constantly a balancing act that we have to consider, we have to consider the timing of regulation, the maturity of standards, the new opportunity of new technology and weigh all of those. Because we can't let the perfect be the enemy of the good and I think David said earlier, we have to crawl then walk, then run without putting braces on the legs, which is I think to your point AJ. So as we go forward with our recommendations, it will be important to have your input and counterpoint to make sure that we are not – we're balancing the requirement to incorporate new technology with the adoption, maturity and ubiquity of existing standards. As well as the instructions that we've been given to be mindful and – of current standards and apply them where we can so that standards do not become a reason to prevent, prohibit or in somewhat delay policy. So this is a balancing act that we all have to work towards.

I very much appreciate your comments and we want to make sure that we incorporate them as we go forward. Are there other comments and considerations from the group, opportunities for other kinds of information or presentations you would like to see prior to our recommendations in the end of September?

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

This is David. I'd like to recommend that this group find a way to get in contact with some of these newer EHR vendors and if they're willing, to get some – get a sense of where this market is going. Because I think the policy right now is a lot has been done, but I'm still sort of worried that policy is way behind where the market's heading –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.

David Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor, American Academy of Family Physicians

– and if we get out of joint and start developing policy, this is related to the earlier comment about standards, if we develop policy that's not suitable for where the bus is skating to or where the bus is going, rather, we won't be able to skate to it. I don't think we're there yet, but, I really think it would be helpful to get the taste of the market. We got some of that last Monday when Jim Ault was in the room and I think that he was pretty vocal about some of these things. But there are at least three or four other companies that I know about, and there are probably others that I don't know about, that might be interesting to talk to. Whether there's a tested business model ultimately – the problem, but we could try, or you could try.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you. Appreciate that. Other comments from the group, areas of consideration; so as a reminder, we have recommendations going forward specifically around patient-generated health data and other Meaningful Use 3 potential recommendations on the immediate short term. As – and I'm – as well as potential impacts around secure messaging and, I'm trying to think off the top of my head, Michelle or Mary Jo, you might help me. The immediate concerns and we hope to have all of our fact finding in our next meeting on the 28th complete, so that in September we can start discussing our – and going forward with the recommendations.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Wes again –

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Sort of building on David's comment, we talk a little bit about levers, and I think it's something we've learned in dealing with ONC, that they necessarily must think in terms of levers and it helps us sort of coral our contributions to make them more useful to ONC to think that way. One of the characteristics of levers is that when it comes to most applications that work on behalf of a consumer, including the consumer who is a patient, there are very few levers.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Um hmm.\

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

And I would propose to embrace that rather than regret that, that is to say, as far as I'm concerned, whether they use – I guess I'm repeating myself. But, once the data is in the hands of the patient, the regulatory process is no longer involved and the provider is absolved of any consequences that come from the patient using their own apps on their own data. I think that may not be a consensus view, but I think it's a point that we should look at carefully and at least present as a point for consideration.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, absolutely. It's as important to identify what is really not applicable to standards or to policy as it is to say what is applicable. But I think that this discussion today has really brought out the idea that although today we're dealing with this idea of binary interchange between the provider and the patient, or applications or PHRs, the future holds much more of a collaborative model. And although we're not seeking those kinds of standards right now in our rule, I think it's something that is important to have in mind. But it shouldn't – that future state collaborative model should not prohibit or stifle the innovation that's coming out of, hey, I can do anything I want with my data. And it's mine to own and that I can decide what my use case is and my sharing is and my information home, Excel might be my PHR, so I think that it is important to be mindful of that. So, we have to allow for public comment, so if there are no other comments or considerations for the group, I'd like to open it up to that. We have – okay.

Public Comment

Rebecca Armendariz – Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue. We have no comment at this time.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

All right. Thank you. Thank you everyone, it was really an informative discussion and very much appreciate both Dr. Kibbe and Dr. Leftwich's participation in this and great times ahead. So thank you very much and the meeting is adjourned.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Thanks Leslie, have a nice weekend.

Leslie Kelly Hall – Senior Vice President, Policy – Healthwise

Thanks all, you too.